another, you just tell us that and we'll make sure we act appropriately.

DR. DRUMMOND: It was more for completeness since you have silicate glass ionomers in phosphates.

DR. TYLENDA: Okay.

DR. DRUMMOND: They are two other cements.

DR. TYLENDA: We can add those to the list, if you want to discuss the appropriate priority, polycarboxylate and resin cements.

DR. DRUMMOND: We would probably suggest that polycarboxylate be low and resin cements be high.

CHAIRMAN ROBERTSON: I see. Polycarboxylate, like zinc silicate cements, would be low.

DR. DUNCANSON: I wanted to ask the Panel about the nomenclature of zinc silicate cement. Are we talking about zinc silicophosphate cement, or are we talking about the aluminosilicate mixture with phosphoric acid?

CHAIRMAN ROBERTSON: Somebody from FDA?

DR. TYLENDA: Actually, Dr. Duncanson, why don't you tell us what you would like? We can subdivide that into two.

DR. DUNCANSON: All right. Since I believe--and my colleagues can correct me, but I believe that the zinc silicophosphate cement is not a big issue as far as a

marketable product, it's off the market, and likewise silicate cement has fallen into disuse a great deal also, so I'm just questioning whether that needs really to be included since we are talking about including the polycarboxylate and the glass ionomer cements which are in use.

CHAIRMAN ROBERTSON: Well, if they are no longer in use--and I will listen to what advice you have there--then it would not seem reasonable to keep them on the ingredient labeling list. It seems like we ought to move them over to the list of things that is not required for labeling. But I will listen to whatever Panel advice there is.

DR. TYLENDA: Consider that we will still accept submissions for those products, and when a submission comes in, we will act appropriately as to which list it is on.

CHAIRMAN ROBERTSON: I guess the question is: If somebody for some reason did submit such a cement or a variant of that cement for use, which list would you want it on? And given the principle that Deb articulated, from a perspective of an outsider here, since it would have long-term contact with mucosa, it would seem that it needs to be on this list and not the other, irrespective of whether it's in use or not.

DR. DUNCANSON: Well, then I would have two categories, the zinc silicophosphate cement and the silicate cement, and I would put them in the low category.

CHAIRMAN ROBERTSON: Speak up.

DR. NORMAN: I don't see that a silicate cement ought to be categorized because they are available in offices that bought them about 20 years ago. But I don't know that they'd be used. I don't know that they're manufactured anymore. The silicate cement powder is very similar to what the glass ionomer cement powder is.

CHAIRMAN ROBERTSON: Well, then, I think that is information that FDA needs to use to refine their list.

MR. ULATOWSKI: I was looking at the list. At first I thought that we had just simply listed the products out by classification name in the regulations, but it looks like as the subcommittee had discussed these issues, it had begun to split things out and divvy things up. So I think if we have things missing or you'd like to sub-categorize further, it's open to whatever you choose.

CHAIRMAN ROBERTSON: Well, I think we'll then follow your advice, split them out and leave to FDA the ability to eliminate one simply since it no longer is available.

All right. Are there any other changes then to

the filling materials?

DR. TYLENDA: As far as the non-Eugenol-containing temporary filling materials, you're not interested at this point in making a recommendation for a priority. Is that correct?

CHAIRMAN ROBERTSON: I certainly am not. I think the subcommittee didn't consider it. I think we just need to put it aside.

DR. DUNCANSON: Well, these cements, I believe, have chemical homologues of Eugenol, and if some of them were to come on--well, it's also important to know what the tissue response would be to those homologues as well as to Eugenol. And that may not be known at this point in time, so perhaps zinc oxide Eugenol and non-Eugenol temporary filling materials could be a category.

CHAIRMAN ROBERTSON: The point here is, however, that the principle, as I understand it, driving these decisions is primarily contact with oral tissues. And those materials that have long-term contact with oral tissues got included on this list. Is that right, Deb?

DR. GREENSPAN: Yes.

CHAIRMAN ROBERTSON: And a temporary filling material would have reasonably long-term contact with oral tissues and, therefore, would be included on the list. And

FDA may choose here to either leave it as it is, zinc oxide Eugenol and other temporary filling materials, or split it out into two categories.

Good. Other comments about filling materials?

[No response.]

CHAIRMAN ROBERTSON: Deb, shall we move on?

DR. GREENSPAN: Moving on to crown and bridge alloys, resins and materials, we looked at the five that are listed, and starting with gold-based alloys, that was given a medium priority; other precious metal alloys, medium priority; base metal alloys, high priority; temporary crown and bridge resin, high priority; and ceramics, low priority.

CHAIRMAN ROBERTSON: Comments from the Panel? Changes? Comfortable?

[No response.]

CHAIRMAN ROBERTSON: Full and partial denture materials.

DR. GREENSPAN: We looked at those materials that were used with full and partial dentures, so we included full and partial dentures in one group. Precision attachments, low; preformed clasp, low; hydrophilic resin coatings, high; denture adhesives, low. And then the following OTC preparations: denture cleansers, high; denture pads and cushions, high; denture reliners, high; and

denture repair kits, high.

Preformed gold denture teeth, low; preformed plastic denture teeth, low; partially fabricated denture kit, low; relining, repairing, or rebasing resins, including denture acrylic, high; porcelain teeth, low.

CHAIRMAN ROBERTSON: Any additions, changes, comments?

[No response.]

CHAIRMAN ROBERTSON: Endodontic materials.

DR. GREENSPAN: Root canal post, low; root canal filling resin, high; silver points, low; Gutta percha, low; stabilizing splint, high.

CHAIRMAN ROBERTSON: Stabilizing splint?

DR. DUNCANSON: Because of the resin--

CHAIRMAN ROBERTSON: Wire and acrylic?

DR. GREENSPAN: Yes.

CHAIRMAN ROBERTSON: Okay. Comments, concerns, changes?

[No response.]

CHAIRMAN ROBERTSON: Orthodontic materials.

DR. GREENSPAN: Do we want to add as a category here endodontic sealers?

CHAIRMAN ROBERTSON: We can recommend to FDA that they add endodontic sealers. And its priority? High.

Based on your notions of zinc oxide Eugenol before. Good.

DR. GREENSPAN: Orthodontic materials. Bracket adhesive resin and tooth conditioner, high; band material, low; metal brackets, low; plastic brackets, low; spring tube, expansion screws, and wires, low; ceramic bracket, low.

CHAIRMAN ROBERTSON: Changes, additions, concerns, amendments?

[No response.]

DR. GREENSPAN: We then come to a group of items that were put under the category other materials. They were all considered because of length of time that they would be in contact with human tissues or else the possibility of damage and, therefore, contact with human tissue.

The first one was the elastomeric impression material, which was high; oral cavity polishing agent, low; abrasive disk, low; abrasive point, low; a caries detection device that comes into contact with the mucosa, low; resin impression tray material, medium; intraoral ligature and wire lock, high; extraoral dental headgear, low; teething ring, low; ultraviolet light for polymerization, low; bite registration material, high; rubber dam, high; silicate protector, high; and intraoral dental wax, low.

CHAIRMAN ROBERTSON: I guess I have to ask a

question about intraoral ligature and wire lock. Lou, help.

DR. SINGLETON: That is a maxillofacial type of device that would be used to bring two bony sections into apposition and fixate them. If one of our oral surgeons is here, is Sue Runner here, by any chance?

CHAIRMAN ROBERTSON: Well, Willie is here. Does that make sense to you?

DR. STEPHENS: Is that already covered in the first section in intraosseous fixation?

DR. GREENSPAN: I think it was included in other materials because of the way that it was listed. So if it is felt that that is more appropriately moved--although it strictly speaking isn't an implant, I think that's why we didn't leave it under implants and, rather, why it was left under other materials. The rationale for giving it a high priority was based on what we were doing with the implant materials.

DR. SINGLETON: It might be more appropriate to list it under the implant section, actually.

DR. GREENSPAN: All right.

CHAIRMAN ROBERTSON: Good. Any other question? Dr. Patters?

DR. PATTERS: Yes, the ultraviolet light for polymerization, it's not clear to me why we would not want

to know the materials that it's constructed from, or we don't want to know the materials that a saliva ejector is constructed from, that being in contact much longer.

CHAIRMAN ROBERTSON: Yes.

DR. NORMAN: I don't think the light would ever-- should ever be in contact with tissue, and the part that might come in contact with tissue would be the stainless steel covering. I don't think that it would have any bearing on any tissues.

DR. PATTERS: Is there a reason to recommend labeling for such?

CHAIRMAN ROBERTSON: The members of the subcommittee need to dredge back into their memories.

DR. GREENSPAN: Into their collective memories, yes.

DR. DRUMMOND: Actually, I have another point. The one, if we're really going to talk about it, should be a visible light, because ultraviolet light is not used that much anymore, anyway.

CHAIRMAN ROBERTSON: Right.

DR. DRUMMOND: So the issue is really visible lights.

DR. GREENSPAN: I don't remember why it was there without looking back at some of the discussions that came

up, or whether there was the possibility for mucosal damage if it were misused. It may be one of the reasons.

DR. PATTERS: How does that differ, for instance, from a facebow?

DR. GREENSPAN: Yes, if it's misuse.

DR. PATTERS: A facebow is not recommended for labeling.

DR. GREENSPAN: Right.

CHAIRMAN ROBERTSON: And it's not an ingredient--

DR. GREENSPAN: No.

CHAIRMAN ROBERTSON: --in the strict sense, that is causing that damage. Unless the emissions are considered an ingredient.

DR. SINGLETON: And the emissions portion of the device would be covered in another part of the regulation, anyway.

CHAIRMAN ROBERTSON: So the emissions would not be considered an ingredient.

DR. SINGLETON: Would not be.

CHAIRMAN ROBERTSON: Under those conditions, I guess I agree that it should not be here.

DR. GREENSPAN: I have no problem with removing it.

DR. DRUMMOND: None.

DR. NORMAN: None.

CHAIRMAN ROBERTSON: Consensus. Actually, we'll get it off the list, but a note to FDA that ultraviolet as the designator here may not be appropriate anymore, and curing light or whatever, a more appropriate term might be better.

MR. HLAVINKA: We have the ultraviolet under a 21 CFR regulation, but no one uses them anymore. Everybody uses filters for light, so everything is vis now, but we just don't have a regulation for it. So it might be an oxymoron, we find these things substantially equivalent to UV, even though there's none.

I just noticed here, could we return to full and partial denture material?

CHAIRMAN ROBERTSON: Sure.

MR. HLAVINKA: On the partially fabricated denture kit, and it is in low. Let me read you our regulation for that. A partially fabricated denture kit is a device composed of connected preformed teeth that is intended for use in construction of a denture. A denture base is constructed using the patient's mouth as a mold by partially polymerizing the resin denture base materials while the materials are in contact with the oral tissues. After the denture base is constructed, the connective preformed teeth

are chemically bonded to the base. Because of the term partial polymerization within the patient's mouth, instead of complete.

DR. GREENSPAN: Can the panel look at that again? I think that we might want to reconsider changing that priority to high because of the procedures that are carried on intraorally.

CHAIRMAN ROBERTSON: One hopes this is silicate revisited, but I think we used the same rules. Is there consensus that we change the priority to high, given what was just read to us?

DR. SINGLETON: Well, one thing you might want to consider also is that this particular device does not include, from what I can gather, relining, repairing, and rebasing resin. That would be separate and apart from this device. In other words, you'd have to incorporate that into the partial denture. And the relining, repairing, and rebasing resin already is in high priority.

DR. GREENSPAN: Yes.

DR. SINGLETON: So you might want to consider that.

DR. NORMAN: If the kit comes with its resin, with its--

DR. GREENSPAN: Yes.

DR. NORMAN: --auto-polymerizing resin system, then it ought to be in a high category.

CHAIRMAN ROBERTSON: And everybody is agreed? Good. We'll change that.

Any other comments on the other materials? Are we comfortable with those given the general principles that we're trying to follow here?

[No response.]

DR. PATTERS: Could I ask that the Panel just take one more look at denture adhesives and see if they're comfortable with low priority?

CHAIRMAN ROBERTSON: Where, Mark?

DR. PATTERS: Full and partial denture materials, fourth item, denture adhesives. In my mind, these are in contact with mucosa for a relatively long period of time; in some cases, misused could be all the time. I don't know what the incidence of sensitivity to these agents are.

DR. NORMAN: They're reasonably high molecular weight polymers, and most of them are--I can't think of any that are not this type of structure right now. The allergic response to this would be very, very low. Irritation can occur, but that's not due to the adhesive per se.

DR. PATTERS: If the Panel is comfortable, I'm comfortable.

CHAIRMAN ROBERTSON: Good. So I don't hear any suggestion to change that from its present low priority. Is that correct?

[No response.]

CHAIRMAN ROBERTSON: Good. Any other changes, additions?

[No response.]

CHAIRMAN ROBERTSON: Good. Then--

DR. GREENSPAN: Do we want to look at the things we didn't consider?

CHAIRMAN ROBERTSON: No. I think what we might--you mean because we might move some back to this list? Good point. Then we'll move on to dental devices not recommended for ingredient labeling. Maybe I'll just read them quickly one at a time, and the question everybody asks themselves is: Given the principles articulated by the subcommittee, are there any here that we should consider moving to our list of dental devices recommended for ingredient labeling?

Paper saliva ejector, cotton roll; dental amalgamator, AC powered; dental handpiece and accessories; gingival fluid measurer--by your silence here--jump in if there's one that you're concerned about--pulp tester; electrode gel for pulp tester; extraoral source X-ray system; intraoral source X-ray system; dental X-ray exposure

alignment device; lead-lined X-ray position indicator; dental X-ray film holder; mercury and alloy dispenser; dental amalgam capsule; resin applicator; articulate; facebow; dental bur, and there's a note that with regard to surgical burs, the subcommittee wants to seek to establish consistency of policy with the Orthopedic Devices Branch. Any update on that?

[No response.]

CHAIRMAN ROBERTSON: No.

Mechanical denture cleaner; pantograph; bone cutting instruments and accessories; powered bone drill; gas-powered jet injector; spring-powered jet injector; dental hand instruments; fiber optic dental light; dental operating unit; dental injecting needle; rotary scaler; ultrasonic scaler; dental electrosurgical device; airbrush; anesthetic warmer; articulate paper, dental chair; rubber dam accessories.

Where did rubber dam in itself go?

DR. NORMAN: It went in high because of latex.

CHAIRMAN ROBERTSON: Okay, good.

Paper points; dental floss--

MR. ULATOWSKI: Mr. Chairman?

CHAIRMAN ROBERTSON: Yes.

MR. ULATOWSKI: In regard to dental floss, I know

there was some discussion in the past. Just a caveat on dental floss. From time to time, we receive applications for dental floss with fluoride and perhaps in the future other therapeutic agents. We have particular concerns about those ingredients and labeling for therapeutic ingredients and particular concerns about clinical studies and other aspects.

CHAIRMAN ROBERTSON: Yes, but not the dental floss, which is--

MR. ULATOWSKI: Per se, right. Not the base floss.

CHAIRMAN ROBERTSON: The point here--right.

DR. GREENSPAN: I seem to remember that in our discussions those claims would be--there is another mechanisms for dealing with those claims and that those products would be considered in that appropriate category rather than dental floss just on its own.

MR. HLAVINKA: That's correct.

CHAIRMAN ROBERTSON: Dental floss was the vehicle.

MR. HLAVINKA: There was a recent publication in the 21 CFR whereby the agency redefined dental floss. It has to be totally inert. Any other additive, it's no longer a 510(k).

CHAIRMAN ROBERTSON: And that's the context in

which this dental floss appears.

Massaging pick; boiling water sterilizer--I remember those; I remember silicate, too. Endodontic dry heat sterilizer; manual toothbrush.

DR. GREENSPAN: Do you remember that?

[Laughter.]

CHAIRMAN ROBERTSON: Good. And now we've added the ultraviolet light. Good.

DR. FRAZIER: Mr. Chairman, could we just for a moment go back to denture adhesives?

CHAIRMAN ROBERTSON: Sure.

DR. FRAZIER: Under full and partial denture materials. I have just been thinking about the length of time that these adhesives could be in someone's mouth, and I would just like to hear a more full discussion about the low versus medium or high priority for labeling.

DR. NORMAN: I don't have anything to add. I think they're low priorities. I do not see them to be--

CHAIRMAN ROBERTSON: Could you get the mike?

DR. NORMAN: Yes.

DR. FRAZIER: What do they contain?

DR. NORMAN: As far as I know, all of them contain a petrolatum base, and FDA may want to talk about this, because petrolatum is now being looked at with a different

viewpoint. But the actual material that is used to hold the denture in place is hydrophilic resin. Most of them were initially naturally occurring gums. Those have been replaced. I don't know that there's anything on the market at the present time that contains a natural gum.

CHAIRMAN ROBERTSON: Is there anybody in the audience who can satisfy the concerns of our public representative about the long-term exposure of mucosa to dental adhesives?

Well, we've done the best we can.

DR. FRAZIER: What is petrolatum?

DR. SINGLETON: Maybe I could just add something. I think in this particular case perhaps you ought to consider the possibility of the reaction to ingestion, not just to reaction of local tissue. I think long-term ingestion of the material may be a factor.

CHAIRMAN ROBERTSON: My sense is that the expertise herein assembled is insufficient to answer the question that you addressed, with the exception that it has been noted in the literature--

DR. NORMAN: There are people who put in as much as a gram of material at a particular time in an application. The amount that in an ill-fitting denture may be sufficient would be half that. So the great majority of

the material that you're ingesting would be petrolatum, and the other's a resin that's nonreactive from the information I at least have been able to get. I have looked at a lot of these over the years, and I don't recall any of the biological information supplied to me that shows any toxicity.

CHAIRMAN ROBERTSON: Okay.

DR. GREENSPAN: I would raise just one thought for this. The fact that it's--perhaps we don't have sufficient data, but also should the possibility for abuse of this product concern us, the possibility for overuse or misuse? Or is that already taken care of in the way that the product is packaged? Should we move this from a low to a medium priority, or do we feel that there are no data to suggest that we should do that?

CHAIRMAN ROBERTSON: My only observation, which I probably should not make, is that I'm quite proud of the notion that the need for such devices decreases every year.

DR. GREENSPAN: I know we felt when we first looked at this that because of the type of material, we felt that the priority was low.

DR. FRAZIER: But at the same time, we have been talking about the principle that we were trying to use of being length of contact rather than--

DR. GREENSPAN: And materials that produce mucosal response, if it's mucosal contact. You know, plastic teeth are in contact for a long time, but we gave them a low priority.

DR. BOUWSMA: I'm not aware of any of the safety issues associated with the denture adhesives, but it's one thing that I can provide perhaps at the next meeting. We do accumulate information like that, and I can bring an answer to that question.

DR. FRAZIER: The reason I brought it up is simply because it looks so strange on a listing to have all of the other OTC denture-related products be high, but it's low. I don't have any particular knowledge that it should be medium or high; it is just that it looks kind of strange.

DR. BOUWSMA: I think that was based on the safety concerns more so with the others rather than with the adhesive that's...

MR. HLAVINKA: The adhesive is furnished in a finished configuration while all the other ones are--you make them yourself, so to speak. It is in a kit, all those other OTCs.

CHAIRMAN ROBERTSON: Other concerns?

[No response.]

CHAIRMAN ROBERTSON: Then may I have a motion to

recommend these dental devices to the FDA for use in whatever approach FDA chooses or chooses not to take in device labeling? This is a recommended list of materials based in general on the principle of contact with oral tissues in categories of implant materials, in filling materials with the modification of the definition of cements, in crown and bridge alloy resins and materials, full and partial denture materials, with a change of partially fabricated denture kits priority to high, endodontic materials with the additional of endodontic sealers with a priority of high, orthodontic materials and other materials, intraoral ligature and wire lock, it's moved to the category of implants, and ultraviolet light for polymerization moves off the list.

DR. DRUMMOND: I'll make the motion.

CHAIRMAN ROBERTSON: Moved.

DR. PATTERS: Second.

CHAIRMAN ROBERTSON: And seconded by Dr. Patters.

Now, any discussion? And in the discussion, I think it needs to be said that we're responding to a request by FDA for a list based on some kind of principle. This is in no way meant to either approve or disapprove the notion of labeling.

All in favor of the motion, please raise your

hand.

[A show of hands.]

CHAIRMAN ROBERTSON: Three, four, five. There is unanimous support for the motion, and the motion carries--with considerable excitement.

[Laughter.]

CHAIRMAN ROBERTSON: We now will adjourn until--captain?

DR. TYLENDA: 1:45.

CHAIRMAN ROBERTSON: Until 1:45. Okay, that gives us an hour and 15 minutes.

[Whereupon a luncheon recess was taken to reconvene at 1:45 p.m., this same day.]

A F T E R N O O N S E S S I O N

DR. ROBERTSON: Welcome back. We will now move to a discussion of a Guidance Document for Dental Handpieces. We will start the open public hearing with Ms. Dawn Johnson from Midwest. Welcome.

MS. JOHNSON: Thank you. I am just going to pass out a copy of what I am saying.

I am Dawn Johnson. I am with Midwest Dental Products. We are a division of Dentsply and we are the largest U.S. manufacturer of dental handpieces, high and low speed.

We would first like to thank the FDA for becoming more involved in handpiece standards. There is a lot of confusion and misinformation around handpieces and the proper use and care of them. As the market share leader, we find we are often caught in the middle of a lot of this information. We welcome some attention to the handpiece product category and hope that FDA initiatives will help to reduce misinformation and improve the credibility of those companies making an effort to sell products that are safe, effective, and with claims that are honestly communicated to the dental profession.

We also appreciate the opportunity to share our issues regarding the proposed guidelines. We have several

concerns and questions relative to the current proposal and will share them in the hopes that these concerns will be considered in drafting the final guidelines.

There are four areas we will cover. They are the product performance standards, sterilization efficacy testing and assurances, labeling requirements, and the impact of sterilizers and accessory products, and also after-market remanufacture of handpieces have on handpiece safety.

We understand that the FDA's primary responsibility is to protect the consumer regarding the safety of products within its jurisdiction. It is our understanding that performance standards are required for Class II and Class III medical devices but not for Class I devices. Given the handpiece is a Class I device, our first concern with the proposed standard is with the performance requirements which are included in the document. We understand and concur with the FDA review of safety-related performance issues but we are concerned with review of product performance issues completely unrelated to either the product's safety or its ability to perform its intended function.

Based on 68 years of handpiece design and manufacturing, we believe that the primary safety concerns

relative to handpieces are bur retention, cooling of the tooth surface, overheating at the cap, use for unintended procedures, and potential for disease transmission.

The following are specific performance inclusions to the proposed guideline which we would like reconsidered. These are inclusions which we believe relate only to performance and not to performance relative to product safety.

The first is the use of the ISO as a part of the guideline, and I have several points on the ISO. One is, ISO standards are designed to harmonize testing and device interface compatibility, not safety. Included in the ISO are many performance criteria which do not provide value relative to product safety.

The ISO is a voluntary compliance standard; it is not mandatory. Depending on which criteria of an ISO standard, many of the handpieces used and sold in the U.S. may not be in compliance with the ISO. These product differences versus the ISO are market-driven preferences versus safety-related product issues.

The ISO standard is a dynamic document subject to change. In fact, standard 7785-1, which is referred to on page three of the proposed guideline, is a proposed standard which has not yet been approved. The U.S. can and may

choose not to adopt future proposals, but the way the current guideline or proposed guideline is written, the product may be challenged on non-conformance to future and unknown standards that would be passed on future ISOs.

We request that the FDA select those portions of the ISO which relate to safety issues and include them in the guideline but exclude non-safety-related data. We also request that the FDA either insert relevant text into the guideline or specify the date of the ISO revision to be referenced in the guideline to ensure that we are not forced to comply with future, unknown changes to the ISO standard.

Second on performance is proposed light output and light measurement at submission. This requirement appears to be performance versus safety driven. We are not aware of any safety issue related to the amount of light projected by the handpiece. Over half of the handpieces currently purchased and used in the U.S. do not even offer a light feature. Many dental schools teach dentistry using non-lighted handpieces and dentists continue to choose this avenue out of both familiarity and also to reduce costs.

The proposed light output standard references 10,000 lux as required light output, but we are unaware of any study which defines light output relative to consumer safety or that would support 10,000 lux being a minimal

requirement to ensure safe use.

We believe light output measurement is not a safety issue and we would like to see it eliminated from the final handpiece guideline. If the FDA determines that there is a related safety issue and is determined to keep it in the guideline, we request clarification on light measurement relative to how and where the light should be measured. This is to ensure consistency among manufacturers.

Two other issues on performance, one is the handpiece angle of visibility, which is included as a criteria. Again, we are unaware of any safety issue relative to the stated angle of measurement, and we are also unaware of any study which would suggest a safe versus unsafe angle, what that angle would be, so we do not see the purpose of this requirement and suggest it be deleted from the final guideline.

There is an additional performance issue about 12-ounce force on a push-button cap. We agree that a manufacturer should ensure lack of heat generation at the cap of the handpiece but we believe the 12-ounce button force is one avenue to that means and the guideline should request test submission on heat generation data, not impose a design tolerance to be followed.

On the subject of sterilization testing and

assurances, we believe the testing requirement for a manufacturer to confirm the sterilizability of a handpiece is a prudent requirement for the FDA and for the manufacturers. We would like to clarify several issues, though, around validation protocols.

First, we would recommend that the guideline require three runs of ten handpieces versus three runs of three, only in that gives us statistical significance and we would be more comfortable with that data.

We need clarification as a handpiece manufacturer on the definition of permissible load.

Then finally, as a handpiece manufacturer, we will be able to test a limited number and types of sterilizers. We would choose standard, conventional sterilization devices. We would hope that any new sterilizer entering the market as a device which can sterilize handpieces would be required to perform the same sterilization protocols on handpieces as the handpiece manufacturer is asked to perform. We are just not sure where the liability is here between the two companies or between the two products. We want to make sure that our testing is mated at some point so that we are all saying the same thing and testing to the same degree.

On reprocessing and labeling requirements, we

believe submission of proof that our product can be rendered sterile under a given set of sterilization parameters is an important safety issue and should be a requirement to obtain a 510(k). We believe that the number of reprocessing cycles through sterilization is an economic and performance issue, not a safety issue. We would like the panel to consider the following.

First of all, from an effectiveness standpoint, the required number of reprocessing cycles is primarily an economic issue, not a performance or a safety issue. Should a manufacturer choose to develop a $50 handpiece which could be reprocessed 100 times and then thrown away, the dentist may very well be pleased with the performance because the economics would be superior to higher-priced units reprocessed through more cycles. For instance, it would be economically better than a handpiece that he purchased for $500 that gave him 600 cycles. So we would like the FDA to consider that reprocessing is primarily economic.

Secondly, sterilization may accelerate handpiece failure, but the mechanical degradation and the mode of failure is not different than it was pre-sterilization. The current concern with reprocessing information required in both the validation and labeling sections of the proposed guideline suggests that the failure mode is changed and is

unsafe as a result of the reprocessing.

The proposed guideline requires all manufacturers to publish their reprocessing information on the package label. We do not believe that an accurate or clinically-relevant measurement of reprocessing life expectancy is attainable and believe an attempt to communicate such information via product labeling is extremely misleading to the dentist.

The labeling of reprocessing cycles suggests that heat sterilization is the sole input to handpiece life expectancy and handpiece failure. In fact, there are significant variations in handpiece life expectancy based on other variables. These variables include but are not limited to the type of practice, whether it is a pedodontist or a crown and bridge practice; the degree of pressure applied by the individual practitioner; the staff maintenance procedures; the shank quality, shape, and length of burs and diamonds used in the handpiece, and the delivery unit air pressure. Each of these variables are outside of the handpiece manufacturer's control and are beyond any measurement via the testing of reprocessing cycles.

We strongly suggest that emphasis on the number of reprocessing cycles be reconsidered and excluded from the final guideline. We also believe including laboratory

testing data in our instructions which claims an expected number of reprocessing cycles is extremely misleading and will misrepresent the product to the dentist. We do not believe this should be required on the labeling. We do believe if a manufacturer chooses to make a reprocessing claim, that claim should be supported by test data and the testing required for such a claim should not be accelerated.

Finally, if the FDA decides to include reprocessing considerations in the final guideline and allows accelerated testing of reprocessing cycles, a definite limit should be set on how much acceleration is allowed to ensure parity testing among manufacturers.

One other thing that is a little bit outside of this but we would like to bring up, in the interest of safety, we believe the FDA should have equal if not more concern around the remanufacture of handpieces as it does around new products. We estimate that approximately 50 percent of U.S. handpiece repairs are done by other than the manufacturer using non-manufacturer parts, processes, and specifications. We also believe the handpiece repair market is as large or larger a market than the new product market.

This means that roughly half of the handpieces in use today and those that will be in use in the future are remanufactured in some way and will not be positively

affected relative to either the safety, sterilization assurance, or labeling as a result of new guidelines. The primary reason to source remanufactured parts is economic.

To highlight the extent of this after-market activity, we believe there are multiple hundreds of repair sources available to the dentist that use parts, processes, and tooling which are not the manufacturer's, are not to manufacturer specification, and are not in compliance with GMPs.

Independent handpiece repair is so common that one organization has sold handpiece franchises throughout the country. These franchises cost $20,000 and provide tools, parts, and three-day training to franchisees to repair handpieces. A device is currently on the market, being sold to dentists, which allows the dentist to repair his own handpiece by removing the failed bearings and pressing on new ones.

Going back to the subject of handpiece safety, the handpiece is generally designed to have the bearing be the failure mode. Bearing failure is generally a safe failure mode. As people remanufacture handpieces, they are depending on other handpiece components to continue to perform safely through other bearing lives and bearing failures. We believe this can be an unsafe condition,

moving the failure mode to a more dangerous mode, such as chuck failure and possible bur ejection.

We request that the FDA do anything within its authority to regulate the handpiece after-market. While we support a higher FDA interest in handpiece products, we also recognize that this adds expense to the handpiece manufacturer. The after-market repair source's competitive advantage is low cost. Further regulating the handpiece manufacturer gives the non-regulated after-market companies an even greater competitive advantage over the manufacturer. This will result in even larger numbers of handpieces being used on patients that are remanufactured, have not proved sterilizability, have not had FDA review, and are not manufactured in accordance with GMP standards.

Given that about one-half of the handpiece in use are remanufactured by non-manufacturers, we believe increased regulation of the handpiece manufacturer without regulation of the after-market puts the manufacturer at a disadvantage and at the same time fails to address what we believe is one of the product category's most significant safety issues.

In addition to the after-market issue, we have also seen a myriad of lubrication products, sterilizers, sterilization aids, et cetera marketed with claims that they

will improve handpiece life. Some of these products have been registered with the FDA. We have asked companies for testing to support these claims but they have not been able to provide them to us. Information, photos, and other material included in their literature clearly misrepresent the product.

Some of the claims that we have seen in print include sterilizers which extend handpiece life four to five times, lubricants which extend handpiece life ten times, et cetera.

As we conduct our sterilizability testing, we will be using our own maintenance products and cannot verify sterilizability when used with other than our own tested accessories. We request that the FDA require companies marketing accessory products making claims relative to handpiece sterilization to follow the same guidelines as the handpiece manufacturer follows with regard to sterilizability and infection control claims.

That summarizes our input to the new guidelines for handpieces. We thank the FDA for its interest in the safety of handpieces and hope that some of the considerations we have presented are of value to the FDA and will be comprehended in the final guideline. Thank you.

DR. ROBERTSON: Thank you very much. That was a

fascinating presentation. It's a more complicated issue than I thought.

I have a quick question. I probably didn't get all of them, but in terms of the performance standards with respect to safety that you outlined, I got retention of the bur and cooling of the tooth and heat generation of the cap and microbial transmission. There may have been a fifth.

MS. JOHNSON: The fifth was use for unintended procedures.

DR. ROBERTSON: Okay.

MS. JOHNSON: Such as an air handpiece for oral surgery or something like that.

DR. ROBERTSON: My question is, to what extent does the sterilization of that handpiece, continued sterilization, to what extent does it affect those safety issues? I mean, you said that it was not possible for you to estimate--

MS. JOHNSON: I understand. I guess our experience, or to the best of our knowledge, and I have two counterparts here, as well, who might be better qualified to answer that, but we don't believe that handpiece sterilization affects safety in any way other than positive, by eliminating the potential for disease transmission.

DR. ROBERTSON: So that--

MS. JOHNSON: We do believe that handpiece sterilization decreases on average, for the average, if you could find him, practitioner, the life of the handpiece between repairs. So we believe that the performance characteristics and the safety issues are unchanged, but the time line of actual use of the handpiece is generally shortened.

DR. ROBERTSON: I understand that, but generally shortened, meaning it doesn't work anymore, or generally shortened meaning there has been an effect because of the sterilization on retention of the bur or cooling or heat generation of the tip?

MS. JOHNSON: No, the general failure is a bearing failure, which was the same failure as anyone would generally have experienced before. I would ask, we have an engineering and a regulatory, but I would say that we have seen no increase in any safety issues such as bur retention, cooling of the tooth surface, use for unintended procedures, or overheating of the cap as a result of handpiece sterilization. What we see is a quicker, a shorter time line for the bearing to fail, and a bearing failure is a slowdown of the speed of the handpiece that ultimately gets to a point where the handpiece doesn't cut but it's not unsafe.

DR. ROBERTSON: So that a number which got pasted on the outside of the handpiece which gave you the number of cycles would not, in fact, relate to the safety issues?

MS. JOHNSON: It's an economic issue. The other thing with the numbering is that we don't know how to get to that number, because if you are a pedodontist, the number is different than if you are a prosthodontist. And if you are a heavy-handed dentist, the number is different than if you are a light-handed dentist, and there are significant differences in each of those areas that we point out. They are not minor differences, they are significant.

DR. ROBERTSON: As a dean, I have the sense that I probably have a laboratory which will give you the lower limit.

MS. JOHNSON: It will give me one or the other, I'm not sure.

DR. ROBERTSON: I mean, I have no doubt that my students will go through the handpiece as fast as any of those other examples you gave, and I could probably determine for you the lower limit. Thank you.

MS. JOHNSON: Any other questions?

DR. TYLENDA: Dawn, you gave some handouts but they didn't reach this far. Do you have any more?

MS. JOHNSON: I think I do. I'll walk them up

right after. Thank you.

DR. ROBERTSON: Wait, wait, any other questions from the panel?

DR. STEPHENS: Does your company and other major manufacturers do your own remanufacturing of handpieces?

MS. JOHNSON: Yes, yes, and I'm being careful for this reason. There are certain products we choose to remanufacture, but most, we choose to put in new components.

DR. STEPHENS: I see.

MS. JOHNSON: You know, to put in a brand new assembly. But I believe that all major handpiece manufacturers selling in the U.S. have their own repair service, and their judgment on when to use a remanufactured part or a new part varies by product and by company. But service is always available from the handpiece manufacturer. It's just more expensive.

DR. STEPHENS: Thank you.

DR. DRUMMOND: This may not be to you. I just have a question of clarification in terms of the FDA's role in this guidance document. Is this document to be for just safety or safety and effectiveness, and would effectiveness include performance standards?

MR. ULATOWSKI: The answer is, it pertains to both aspects. In our evaluation of equivalence, we take a look

at equivalent performance in terms of safety and effectiveness.

DR. ROBERTSON: I think probably the presentations by FDA will maybe try to clarify that and it will be an opportunity for the panel in this new area to see if we can't figure out where we are.

Any other questions from the panel? Dr. Patters?

DR. PATTERS: Your company then has no problem with certification of sterilization and with the drop test, is that correct?

MS. JOHNSON: The certification of sterilization, we have no problem with and we believe it's in both of our interests that we do that testing.

The drop test, I guess I understood to be related to disposable handpieces. Am I misinterpreting?

DR. TYLENDA: That's correct.

MS. JOHNSON: Is that correct? We don't make a disposable handpiece. Our own irrelevant opinion, since we don't make one, is if you drop it and it can't be sterilized, you throw it away, so to drop test it doesn't make any sense because you ought to toss it. But because that's not our product category, I shouldn't have said that, but that's our opinion. Thank you very much.

DR. ROBERTSON: Thank you very much.

Mr. Tom Fise from the American Dental Trade Association?

MR. FISE: I did not want to confuse this with the prior statement, which is why I delayed handing this out.

DR. ROBERTSON: It doesn't guarantee that we won't be confused.

[Pause.]

MR. FISE: Good afternoon. I'm Tom Fise and appear, again, on behalf of the American Dental Trade Association as their Special Counsel on Regulatory Affairs.

The concept of providing guidance documents to help manufacturers understand the issues of keenest interest to FDA in its review of certain product submissions is inherently a good one so long as the purpose of the guidance document is not misunderstood. We have some questions relating both to the specific content of this guidance document as well as to how the document is used by FDA. This guidance document should not be construed as a catalog or checklist of FDA requirements which must be met to secure 510(k) approval for handpieces.

Dental handpieces and their accessories are so-called pre-amendment devices, meaning that they were legally marketed before the 1976 Medical Device Amendments. Dental handpieces on the market at that time, and including any

that have filed one or more subsequent 510(k) notifications of modifications that have been accepted by FDA, are legally marketed today without respect to whether they meet all of the criteria established in the FDA guidance document.

The prospective criteria for having an acceptable 510(k) filing for a new or modified device continues to be whether the device can demonstrate substantial equivalence to a device that is currently legally marketed, and that case may be a pre-1976 device or handpiece. So the idea of an FDA guideline is not a substitute for that legal criteria, which is the limitation that allows someone to come onto the market.

A 510(k) submission that does not meet each and every criterion set out in the 11-page FDA guidance document may still meet the legal requirements for substantial equivalency, and so our first point is that it is important to place the FDA guidance document in the proper context. Complete compliance with the guidance document may constitute a "safe harbor" to acceptability, but compliance with the guidance document is not a sine qua non. It is not the sole pathway to demonstrate substantial equivalency.

We would also like to highlight a few specific items in the FDA guidance document that we believe may be troublesome, and to some extent, a couple of these have been

touched upon previously.

We have noted the sections there, II.B.9. We do not think that the manufacturer should be required to list all accessories or attachments that may be used with the device, as this may include products manufactured by others. A current listing of accessories or attachments that the specific manufacturer may intend to market with that device seems justified.

With respect to II.D.1, we are uncertain with regard to the requirement that hose connections remain intact up to 150 percent of normal operating air pressure. This tolerance level may relate to a voluntary specification, and probably does, to the ISO or ADA/ANSI specs, but there is not a regulatory obligation for handpieces as Class I devices to meet such a voluntary standard.

With respect to II.D.5, as was mentioned before, we are a bit uncertain about the source of the regulatory status of a requirement for a minimum load of 12 ounces on the push button before the release mechanism contacts any rotating parts.

On II.D.6, we are also uncertain of the source or validity of the three-foot drop test requirement. Again, we were not clear until this point that that was limited to

disposables, and so that may be either an error in our reading or might be something that could have some further clarification. Moreover, the requirement for 100 percent pass rate, we had some question about. It says there be a minimum of ten and that all must pass.

With respect to II.E.1, we think this illustrates the difference between guidelines and the legal requirements for substantial equivalency, and we note two specific provisions under this section. The first would require identification of a specific number of reprocessing cycles, and I want to come back to the term reprocessing cycles.

The second would state that any advice to follow the recommendations of the sterilizer manufacturer is inadequate. Now, it is our understanding that, again, in theory, a device can be legally marketed today without either identifying a number of reprocessing cycles and that it could today bear the legend simply to follow the recommendations of the sterilizer manufacturer. So if that device can be legally marketed, there certainly should be able to be a substantially equivalent device that has the same information.

Clearly, if a manufacturer chooses to state a number of reprocessing cycles or cleaning cycles or sterilization cycles, the product must meet that criteria.

And likewise, if the manufacturer does state any instructions beyond following the sterilizer manufacturer's instructions, then the instructions they give must be adequate. However, we don't think that this guideline document can operate to change the rules, as it were, or change the requirements for substantial equivalency.

Moving then to II.E.2.a--I'm sorry to be a little bit convoluted--we do not see the basis on which FDA would maintain with respect to 510(k) demonstrations of substantial equivalency that the manufacturer be required to maintain "a record of the data that show that the handpiece can withstand the number of reprocessing cycles claimed in labeling."

Likewise, we are uncertain about the source or validity and the regulatory basis of the requirement or criteria "with less than ten percent decrease in performance characteristics" that is listed in II.L. Actually, we had some trouble finding Section II.L in the document itself, at least as we received it in advance of the meeting.

Finally, I want to get back to the reprocessing issue and say that, again, we question this requirement or prospective requirement that manufacturers be required to state a number of use or reprocessing cycles that the handpiece can withstand before disposal or repair is

required. Particularly, we are troubled by the use of the term "reprocessing," when what we seem to be referring to is sterilization cycles.

In the FDA's recent publication on good manufacturing practices, the FDA has defined reprocessing this way. Reprocessing means all or part of a manufacturing operation which is intended to correct non-conformance in a component or finished device before distribution. So we think the term reprocessing has a specific meaning that relates to something that happens before the device is sold or redistributed or whatever and does not refer to what happens in the dental office during sterilization.

So we think a correction just in that term is important, and it is important because the term reprocessing is carried on throughout these regulations, so something that is a little clearer, we would be happier with.

In conclusion, we are concerned about potential misunderstandings as well as the potential that the document in its current form might be misapplied, either by manufacturers or by evaluation or compliance staff at FDA. Many of the recommendations in the document, we think, are very valuable.

We would, however, recommend that because of possible misunderstandings that the best thing would be to

add some explanatory language and indicate with absolute clarity that the document defines a safe harbor and establishes targets, that it is not to establish the minimum requirements either for a 510(k) substantial equivalency or for compliance requirements of current products that are on the market. If that cannot be done, then perhaps the document ought to be withdrawn and looked at again. We do believe that the specific areas we have highlighted would merit some further review and consideration.

We appreciate again the chance to present on behalf of ADTA and would be happy to answer any questions.

DR. ROBERTSON: Thank you very much.

Questions from the panel?

[No response.]

DR. ROBERTSON: That was very useful. Thank you. I am sorry?

DR. TYLENDA: I just want to tell Dawn that we were able to get some copies of your presentation made, so you don't have to worry about rooting through your briefcase to find them.

DR. ROBERTSON: Mr. Jeffrey Peinhardt from Den-Tal-Ez?

MR. PEINHARDT: Good afternoon. My name is Jeffrey Peinhardt from Star Dental, which is actually a

subsidiary of Den-Tal-Ez, Incorporated.

I would like to first thank the FDA for generating this draft document. It has been long overdue and needed and we basically agree that we do need a draft document. I appreciate the panel allowing us to review changes that we feel should be necessary.

Dr. Tylenda has distributed copies to the panel dated July 28 of our discussions. We have some areas of concern and I would like to go over these in particular.

Sterilization validation, Section II.E.1, the draft implies the handpiece manufacturers must test every available method of sterilizer, and when combined with other sections, print individual instructions for each. Additionally, if one model differs from another, the draft implies publishing separate instructions for a potential lengthy list of caveats for each individual difference. This would prove overly burdensome to the manufacturer, as a small manufacturer of dental products.

We would suggest FDA recommend a guideline for performance ranges of steam autoclaves, unsaturated chemical vapor sterilizers, and dry heat for handpieces to be tested in. In this way, a generic testing standard can be developed which would enhance the purpose of this document.

What I wasn't aware of is the labeling for

reusable medical handpieces that I picked up this morning. This is section reference Part C, Section 6, which may better describe what the FDA really intends to do as far as the sterilization, what they want the manufacturers to do, so we might want to try to harmonize those two thoughts. I would recommend having the panel review Part C, Section 6, Paragraph G and compare it with Section II.E.1 of the proposed draft.

The next item is also on sterilization validation, II.E.2.a. The draft, in the first paragraph of II.E.2.a, calls upon the manufacturer to be significantly more precise than a dental environment requires. For example, a ten percent reduction in power is probably not subjectively discernible. Additionally, different operators will use their handpieces through varying levels of performance.

We believe the issue here should be safety and efficacy. We would recommend that manufacturers establish a level of performance that is unacceptable and consider that level a failure. Manufacturers can then indicate a mean time between failures specification.

In no circumstance should the failure level represent a level of performance that would compromise safe operation of the handpiece, and that is the real issue here, is safety and efficacy of the product. The mean time

between failures are consistently used in many manufacturing specifications.

The second paragraph in II.E.2.a leaves a great deal of latitude to manufacturers to develop a testing program that could very well compromise or overstate the life or performance expectations of a handpiece. It could also understate life and performance. It is not clear in the proposal.

We would recommend at least a minimum guideline be suggested within the guidance. Care should be taken not to make the suggested guideline in excess of what dental office environments represent.

Lastly, the concerns in the labeling section II.F.3.g, Part 4, basically applied to our first point. In the standard, they want the labeling to reflect all sterilizers be listed and to qualify each sterilizer for our particular product.

While I'm on the subject, I'd just like to address the FDA, if I could, and ask them a question. In Section II.E.2.a, where did the ten percent figure come about, the ten percent reduction in power?

DR. ROBERTSON: I think it is a good question and I think that is a question we will certainly pass along to FDA.

MR. PEINHARDT: Those are the only items. If the panel has any questions for me, I'll certainly try to answer them.

DR. ROBERTSON: There was a statement you made that somehow I missed. It had something to do with making the guidelines in excess of what dental offices represent, and I didn't understand the point you were making there.

MR. PEINHARDT: Okay. Let me go over that again. This is in the section that--were you relating to the discernible, that the dentist would not be able to make a discernible difference?

DR. ROBERTSON: No, you made a statement that these guidelines should not be in excess of what dental offices represent toward the end of your presentation.

MR. PEINHARDT: Okay.

DR. ROBERTSON: I didn't know where you were going with that.

MR. PEINHARDT: That was in the performance area under handpiece testing, the second paragraph of II.E.2.a. This is a section that calls out, in order to minimize the time needed to obtain reprocessing data, accelerated wear testing, so on and so forth, and it leads into the bottom, and load parameters that are typical in a single dental appointment. The emphasis here is this leaves a great deal

of latitude for the dental as a manufacturer.

We feel there should be some sort of a more specific guideline so that a testing program that could compromise or overstate the life of performance of a device, I think there needs to be--and we, Den-Tal-Ez--thinks that there should be some sort of at least a guideline for testing.

DR. ROBERTSON: I'm surprised, but all right. Thank you.

Any other questions?

[No response.]

DR. ROBERTSON: Thank you very much.

MR. PEINHARDT: Thank you.

DR. ROBERTSON: Mr. Steve Jefferies from Dentsply?

MR. JEFFERIES: No, I won't be making comments.

DR. ROBERTSON: Oh, I'm sorry. Well, if Steve doesn't want to talk to us, then is there anyone else who would like to address the panel? Anyone else who would like to address the panel?

[No response.]

DR. ROBERTSON: We will now hear from Dr. Michael Mendelson from FDA.

PRESENTATIONS

DR. MENDELSON: The Dental Handpiece Guidance

Document is directed toward FDA personnel, so that the review of pre-market notifications for 510(k)s will continue to be consistent, and it is designed to help industry so that submissions will be complete. That is, there will be enough information provided initially to allow the reviewer to evaluate the handpiece submission quickly.

The document addresses the following aspects of the 510(k). One, the physical description of the handpiece. Two, identification and description of a predicate device. Three, performance characteristics. Four, labeling. And five, ensuring that the handpiece can be sterilized.

We would like this document to compliment two existing documents that also address infection control. The first document is the draft guideline entitled, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, FDA Reviewer Guidance," which was distributed by the Infection Control Devices Branch of the FDA's Office of Device Evaluation. It provides items such as an overview of device reprocessing steps, instructions, information on documentation of sterilization validation, a check list to encourage consistent reviews by FDA personnel and references.

The second document is Technical Information Report, or TIR, No. 12, entitled "Designing, Testing, and

Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, A Guide for Device Manufacturers," which was published by the Association for the Advancement of Medical Instrumentation, or AAMI, in 1994. According to AAMI, it is intended to, "assist medical device manufacturers in the design, testing, and labeling of devices intended for reuse and reprocessing in health care facilities. Manufacturers may wish to reassess the labeling of existing products in the light of the recommendations of the TIR."

The Centers for Disease Control and Prevention recommends routine heat sterilization between patients of the following three items: High-speed dental handpiece, intra-oral components of low-speed dental handpiece, and reusable prophylaxis angles.

To ensure that handpieces are actually sterilized in the clinical setting is the responsibility of both the manufacturer and the user. The 510(k) should address two basic aspects: One, that it is physically possible to sterilize a handpiece, and two, that the labeling is adequate to allow the user to sterilize properly.

Therefore, the manufacturer should provide instructions on the use, decontamination, sterilization, and state how many times this cycle of use and reprocessing

steps can be repeated before safety or performance deteriorates excessively. If periodic disassembly, lubrication, disposal of components, or other service is needed, the instruction should include this information, also.

Before marketing a handpiece, an applicant must determine that a handpiece can, in fact, be rendered sterile. In other words, microbiological techniques should be used to determine that there is an acceptable probability that all viable forms of microbial life can be removed or destroyed from the handpiece if the manufacturer's instructions are followed. Manufacturers should also perform testing to verify that durability in terms of the number of use and reprocessing cycles claimed in the labeling is accurate.

There are several corrections that I would like to make to this guidance document. One is item II.E.2.a, that addresses the performance characteristics addressed to in the sterilization section. The performance characteristics referred to are listed in item II.D, not L.

DR. TYLENDA: It would be helpful if you gave the page number, also.

DR. MENDELSON: Page nine. Also, in the labeling section--

DR. GREENSPAN: Could you repeat that?

DR. MENDELSON: Sure. When it refers to performance characteristics, it should be making reference to Section II.D, not II.L.

DR. GREENSPAN: Line three.

DR. MENDELSON: I discovered that before this meeting, but it was too late to mail anything out.

Also in the labeling section, II.F.2.a.3, the phrase "maximum number of use reprocessing cycles before disposal or repair is required" should have the word "maximum" deleted.

One note on the labeling section. This is not a sterilization issue. In II.F, item 3, it would be helpful to the user if the instruction manual for a handpiece were supplemented with several items. Therefore, paragraph E, installation and connection instructions, should be modified with the addition of the following basic items. One, the maximum free-running operating speed. Two, the minimum shank length to be fitted inside the chuck. Three, the maximum overall bur length recommended--

DR. TYLENDA: Could you give us the page number that you're on so we could follow along?

DR. MENDELSON: Page ten.

DR. TYLENDA: Page ten, item E?

DR. MENDELSON: Item E, yes, installation and connection instructions. I'll go over them again.

Maximum free-running operating speed was the first. Second, the minimum shank length to be fitted inside the chuck. I believe these items are listed earlier under the section where the handpiece is described to the FDA, but these would abe valuable for the user to prevent safety problems.

DR. TYLENDA: So if you go back to page four under the capital letter B, you want to add some of those items--to copy some of those items into page ten under number E?

DR. MENDELSON: That's right.

DR. TYLENDA: You want to copy item three, item four, item five, item six, right? So this information coming into FDA should also be included in the instructional material for the user?

DR. MENDELSON: I don't think the user would be helped with all of it, but there are certain items that most clinicians would appreciate to prevent bur tips from flying off or other such accidents.

DR. TYLENDA: So those are items--just give us the numbers and we'll just circle them.

DR. MENDELSON: I don't believe maximum operating speed is--it's on page four. Shank length is item number

three. The maximum overall bur length is not in page four. Air pressure range would be on page five. Item seven, and that's it.

Finally, as mentioned, when other guidance documents are presented, the dental handpiece guidance is presented now in draft form because the Dental Devices Branch is interested in the advice offered by panel members and industry. Also, this document is subject to continued changes as knowledge is extended and new designs are presented.

What can the panel do? There are three basic questions. Would this document be helpful to industry? Two, does it provide a strong enough framework upon which an applicant can easily build an adequate pre-market notification? Three, what suggestions for improvement do you have?

We have provided a list of more specific questions to help you make your assessment. There is one correction that needs to be made to these questions. In question number five, the second sentence lost a phrase when it was copied into your packet. If you want to get that out, I'll wait.

[Pause.]

DR. MENDELSON: It should read, "Is it more

appropriate to provide labeling stating the number of cycles a particular model can withstand, subject to forces such as the price consumers are willing to pay and the maintenance steps they are willing to perform?"

DR. GREENSPAN: Could you repeat that, please?

DR. MENDELSON: Sure.

DR. ROBERTSON: Where are you?

DR. MENDELSON: I'm on question five. It's the bottom of the first page of questions.

DR. ROBERTSON: Okay.

DR. MENDELSON: There is a phrase that was missing. "Is it more appropriate to provide labeling stating the number of cycles a particular model can withstand, subject to forces such as the price consumers are willing to pay and the maintenance steps they are willing to perform?"

That's it.

DR. ROBERTSON: Thank you.

I have an initial question, and that was to try to bring you back to this term reprocessing. I was, in fact, digging through this paper and the "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities", an FDA reviewer guidance document from the Office of Device Evaluation in March 1995, in fact, does define reprocessing

as cleaning, disinfecting, and sterilizing. But a companion document, the Technical Information Report, AAMI, 1994, does define reprocessing in the context of repairing.

DR. MENDELSON: I have this document in front of me. It was my understanding that the Technical Information Report chiefly addresses the decontamination and sterilization of reusable devices in the health care site.

DR. ROBERTSON: Somebody raised, and I forget who, maybe it was Tom, a concern about the term. Was it?

MR. FISE: It was.

DR. ROBERTSON: Maybe you could restate that concern and make sure I'm not confused, but I was confused about the use of the term reprocessing.

MR. FISE: Yes. Again, Tom Fise with the American Dental Trade Association.

The point we made is that reprocessing is a term of art that is used with one definition in the GMP document and it relates strictly to activities that occur in the manufacturing plant. We are somewhat concerned that this is confusing enough, that using the same term, even albeit with a different definition, in this document might confuse people, to say that everything that applies to reprocessing in here must apply to what happens in the dental office.

We just think the choice of a different term that

isn't kind of pregnant with other meanings would probably make sense.

DR. ROBERTSON: Dr. Patters? No?

MR. HLAVINKA: We will probably change the terminology to recleaning and resterilization of devices. That way, there won't be any confusion with the reprocessing term.

DR. ROBERTSON: I thought it was an interesting point. I don't care about the terminology, but it would be useful to make it clear.

MR. ULATOWSKI: The term reprocessing has been used in the infection control community to mean sterilization and decontamination, and yes, there is overlap in regard to GMPs. That document on reprocessing is in draft form and we are collecting comments right now and will revise it accordingly. It is a good point and one we'll consider.

DR. ROBERTSON: Any other questions from the panel?

MR. HLAVINKA: One last clarification. This guidance doesn't have anything to do with repair. It's just the reprocessing aspect, recleaning, resterilization. I also want to clarify that.

DR. O'NEILL: I have a question in that regard.

When we are talking about reprocessing and you are talking about renaming that cleaning and resterilization, I think there is more implied in this term of reprocessing and that is cleaning, sterilization, and then general use again. In other words, there was some discussion in these documents about taking a handpiece and sterilizing it 14 times versus taking a handpiece, sterilizing it, using it in a standard situation, then sterilizing again, then using again.

So I think in that term reprocessing, it implies more than just cleaning and sterilizing. It implies standard use of the instrument in between, is that not correct?

MR. ULATOWSKI: That's correct, yes.

DR. O'NEILL: So if you just go back to a term "recleaning and resterilizing", it might lose that other component, is what I'm saying.

MR. HLAVINKA: We'll work on the terminology so it won't be ambiguous.

DR. O'NEILL: Okay.

DR. TYLENDA: The AAMI Technical Information Report dated 1994 that Dr. Mendelson referred to can be purchased from AAMI at a cost of $41 for AAMI members and $62 for non-members.

DR. ROBERTSON: Any other questions?

[No response.]

DR. ROBERTSON: We now have a presentation to the panel by Dr. Chris Miller from the University of Indiana School of Dentistry. Chris?

DR. MILLER: Thank you very much. It's indeed a pleasure and an honor to be here and to talk to such a distinguished panel. It's good to see many of you again.

When the variety of regulations came out in regard to heat processing handpieces, I immediately remembered that many have been doing that for quite a long time, but maybe in the lack of scientific information. So a few years ago, I went to look for some of this scientific information to see if, indeed, there is documentation that we can kill high levels of bacterial spores that are placed inside of handpieces. That information at the time, which was about three years ago, was essentially unavailable except for one publication that I found in a Swedish journal.

So I thought, well, maybe it would be a good idea to begin to generate some of this information. So I would like to present to you some of the work that we have been doing at our lab and simply acknowledge my coworkers here, and also acknowledge the fact that most of this work has been funded, at least in part, from a grant from the American Fund for Dental Health.

The purpose of this initial presentation, or study, I should say, is to determine if the inside of high-speed handpieces can be actually sterilized by steam and unsaturated chemical vapor sterilizers. The inoculum that we have used is the indicated organism for these two methods of sterilization and that is Bacillus stearothermophilus, and as we have used an organic load of ten percent defibrillated sheep blood. Ten percent of the total volume of the spore inoculation contains the sheep blood. As much as possible, the level of the organisms placed into the handpiece units are at six logs, or a million spores per handpiece unit.

Method one, the spores in the blood were placed on turbine fins. The handpiece was assembled and then pre-flushed for five seconds, which simply means it's hooked up to the unit and operated with air and water for five seconds. This was originally used in these early studies to distribute the inoculum fully within the turbine chamber.

Then, in this particular presentation here, spores were then placed into the water line of that same handpiece to test both internal sites of the turbine and the water line. Then the whole handpiece was dried, in this particular situation, at 50 degrees Centigrade for one hour, and then it was individually packaged in paper/plastic peel

pouches and heat processed.

Again, let me kind of visualize again what we did here. Disassembled a handpiece, and here in these tests we were using three different brands of handpieces. We disassembled the handpiece, inoculated the fins of the turbine with a measured amount of our spores and blood suspension of a known concentration and the resistance and so forth, assembled the handpiece as it would be normally used, hooked it up to the water/air lines, flushed it for five seconds with the bur in place, again, simply to distribute the inoculum within the turbine chamber, and we'll see where this causes some methodology problems here, but this was the protocol that we were testing.

Then the handpiece was inoculated internally into the water line with the same inoculum of spores and blood, individually packaged, and then heat processed through a variety of time/temperature combinations. So a pretty straightforward protocol in this particular situation.

After heat processing, we made attempts to recover lives spores. The turbine and the head and the end cap were flushed ten times with 4.0 mL of sterile water. In other words, it was all disassembled and placed in a beaker under a biosafety hood for prevention of contamination and then flushed ten times with a single 4.0 mL volume, to knock the

spores off of the turbine and so forth into the recovery fluid. The water line was then flushed ten times with a separate 4.0 mL volume of sterile water to again recover any live spores remaining.

The recovery fluid was then cultured in double-strength tripticase soy broth, TSB, and incubated at standard temperatures for seven days. A viable cell count on TSA, when that was necessary to verify the challenge level, was again performed at 55 degrees centigrade for seven days. So that's how we recovered the spores to see if we had any sterilization failures.

Again, just a visualization here. Disassemble the handpiece, remove the turbine, place it in the bottom of a beaker, and just flush this ten times, up and down, up and down, to knock the spores off. This is, again, in lieu of submerging the handpiece at the end for culturing. And again, flushing the water line into a separate beaker and then culturing this recovery fluid.

The results of this particular series of testing. Using spores and ten percent blood, a gravity steam sterilizer operating at 121 degrees Centigrade for 30 minutes--now, we did not have any thermocouples inside of the sterilizers that we used. We didn't do that. It's a thing that we should do, but it hasn't been done. So we

can't verify the internal temperatures here. However, these sterilizers have been verified by routine spore testing as well as all of our control spore testing along with the actual experiments.

On the left side here, we see simply three brands of handpieces, labeled A, B, and C. We just happened to do B twice in this particular set of experiments. The mean log of the base ten challenge in the turbine, we could recover five to six logs of spores. And in the water line, about the same level. So we had a fairly good challenge, real close in almost all instances of a million spores per handpiece.

Over here, we have failures. A failure is growth of the spores that were confirmed as the test organism from any single handpiece.

So in the turbine area, for example, in this first line here, we did a total of 12 handpieces that were inoculated both in the turbine and the water line. In culturing the turbines after heat processing, six of those 12 handpieces had live spores. In this particular case, three of the 12 handpieces had live spores remaining in the water line.

In this sample down here with brand B, one of the 12 handpieces failed with still growth present in the

turbine, and here, three of the 12 handpieces failed with growth in the water line. When we repeat the same handpiece in a separate cycle, again, zero of 12 and two of 12 failures. In type C, zero of 12 and two of 12.

So, clearly, there are some differences, obviously, between handpieces, and this is an important concept to understand, because the internal situation is different and the availability and access of a sterilizing agent to the inside is certainly going to be affected by the physical arrangement of the internal portions.

So if you look at the total number of handpieces in this particular set of information here, there are 48 of them tested and 29 percent of them failed.

DR. ROBERTSON: While you have the slide up, can I just ask a quick question?

DR. MILLER: Yes. Let me put it back here.

DR. ROBERTSON: That's all right. You can just answer the question. Are there handpieces in this run that were not contaminated with spores but went through the whole procedure that these did? Are there any control handpieces where there were no spores, there was no contamination of the handpiece?

DR. MILLER: No.

DR. ROBERTSON: No?

DR. MILLER: Well, we verified sterility of the handpieces beforehand, yes. In other words, what we do is in preparation for these handpieces to--

DR. ROBERTSON: Yes, I understand. So there is not a parallel set of handpieces that were sham contaminated and then carried all the way through this same--

DR. MILLER: Oh, yes, that were contaminated, yes.

DR. ROBERTSON: No, not contaminated.

DR. MILLER: Oh, no. Not contaminated, no. There's nothing to recover in an uncontaminated handpiece.

DR. ROBERTSON: Dr. Rosan?

DR. ROSAN: Yes, these are the presence or absence of any organisms in terms of failure, is that correct?

DR. MILLER: That's right.

DR. ROSAN: Whether there was growth or no growth?

DR. MILLER: Yes.

DR. ROSAN: And that was carried out in a broth rather than a plate? They were not counted, in other words? You just--

DR. MILLER: No, this was qualitative, growth or no growth. The entire recovery fluid was cultured to get maximum chance for organisms to grow in recovery.

Yes, sir, Mark?

DR. PATTERS: How can you be certain that the

bacteria didn't come from the water line and is not part of your inoculum at all?

DR. MILLER: That's a good question. These particular spores, the Bacillus stearothermophilus, are not common environmental spores. You could probably find them if you looked hard enough, but in all of the water that I personally have cultured from dental units, we have never found anything that grows at 55 degrees Centigrade, so--

DR. ROBERTSON: But you were using the spores as part of this experiment.

DR. MILLER: Oh, absolutely.

DR. ROBERTSON: You had the inoculum around, so there was a source of these spores that could have well been your experimental design, a mistake--

DR. MILLER: Sure. The spores are in our laboratory and we're using them.

DR. ROBERTSON: Yes.

DR. MILLER: You could have experimental error, yes, accidental contamination with the test organism.

DR. ROBERTSON: Who knows what.

DR. MILLER: Understand, thank you.

Let's look at the same set of conditions except under a different sterilization method. Here we have 134 degrees Centigrade for 30 minutes. This is a real serious

challenge here, and this is a pretty serious approach to killing microbes, at 134 degrees Centigrade for 30 minutes.

So again, similar challenge failures. A few failures, still, even at this maximum temperature. In this case, three of the 12, and here, three of the 12, two of the 12, one of the 12, and again, if you look at the total number of handpieces in this particular analysis of being 48, 17 percent of them end up failing.

A third method of sterilization, or condition of sterilization, the unsaturated chemical vapor sterilizer operating at its normal cycle time of 20 minutes at 134 degrees Centigrade. Again, with the three brands, we see a considerably larger number of failures here, some failures here, none here. In this particular case, the water lines were not tested because they became plugged with this massive amount of spores and blood placed into them and then drying. We couldn't even get samples out of them, so that caused us some procedural problems, too.

When we got this information, this was instilled into our thinking, some concerns that, well, maybe we can't kill organisms inside these handpieces very reliably, so not as an indication for sterilizability but for some general information, what if saliva gets back up inside these handpieces, as we presume it does in many instances. Can we

kill the organisms that are present in normal saliva?

So we thought we would do a test using the identical conditions, except instead of using spores, simply use raw saliva. The raw saliva that we were using had about a million CFUs per milliliter, a million organisms per milliliter, but, of course, by the time you put them into the handpieces with the small volume, the challenge drops way down.

But nevertheless, I think it's important to note that even in this rather standard steam sterilization cycle of 121 degrees Centigrade for 30 minutes, we were able to show at least to be able to kill salivary organisms, which, again, are not challenging, but I think this is very important information to have in regard to efficacy and the reasons for heat processing handpieces in the private practice. It is important to do this. While we may not be able to show right now, at least, that we can kill spores in all test handpieces, we certainly can apparently kill salivary organisms.

DR. ROBERTSON: Chris, what does controls mean in this context?

DR. MILLER: The controls were inoculated handpieces that were not heat processed so we could measure the level of the challenge.

DR. GREENSPAN: What type of organisms did you recover from your controls?

DR. MILLER: We didn't do an analysis of the colonies, being so there were a tremendously large number in raw saliva.

DR. GREENSPAN: So you essentially were just doing bacterial testing--

DR. MILLER: Total counts, total counts.

DR. GREENSPAN: You weren't doing viral testing at all, just bacterial counts?

DR. MILLER: No, no, no, strictly bacteria, salivary bacteria.

A second method of testing handpiece sterilization has been used in a couple of instances and we thought we would like to look at that. In this particular method, the turbine was completely removed from the handpiece and replaced with one spore strip cut into six pieces. Then the end cap was placed back on. The bur hole was then sealed with a rubber dam patch. The head was wrapped three times with autoclave tape. It was individually packed and heat processed, again, looking at another challenge of the handpiece system.

Again, the turbine was removed. A spore strip was aseptically cut up into six pieces and placed into the

chamber and then the end cap placed back on. A rubber patch placed over the bur hole and then wrapped with tape to secure the rubber patch in place, again, to supposedly enhance the challenge to this system. Individually packaged and heat processed.

Culturing of spores, again, here, we simply aseptically removed the cut-up spore strip and cultured it in broth, as one would normally culture a spore strip. This, we found, was very much less challenging than the previous method we described of using a suspension of spores and blood.

The gravity steam sterilizer, 121 degrees Centigrade for 15 minutes or 30 minutes, we found total kill in all of the test handpieces, 12 in each of the runs. So again, less challenging, which we kind of suspected, but again, this method has been used in a couple of instances and we wanted to look at it.

Using 134 degrees Centigrade and steamed 15 to 30 minutes, again, no failures.

And in an unsaturated chemical vapor sterilizer at 134, pretty good. A couple of failures in one instance here at their normal half-cycle of ten minutes.

A third method, which is very much like the first except a couple of variations here and there in the drying.

Here, we used spores and blood placed on the turbine fins. We either pre-flushed or not pre-flushed, which means, again, circulating the spores inside the chamber.

The drying here was at a different temperature. Drying spores at 50 degrees Centigrade, some people may feel could begin to enhance their germination in the drying process and make them less susceptible to killing when you put them in a sterilizer. So we were previously drying at 50 degrees Centigrade, so we thought, well, we don't know what that effect is, but let's drop the drying temperature down to room temperature. We know the spores won't germinate there, and for 24 hours. Then we individually packaged and heat processed.

The effect of pre-flushing on killing, we had the assumption that if you put spores on the turbine fin and then you operate that handpiece for a little bit, you'll blow all the spores around essentially inside the turbine chamber and get them all into the nooks and crannies. It will probably make a pretty good challenge. And I think the data suggests that that's indeed the case.

Here's a handpiece, type B, for example, that was not pre-flushed, and of those five handpieces, we detected live spores on the turbine fins of one. The same handpieces that were pre-flushed for five seconds and then heat

processed, we found three of the five failures--not a tremendously large number of samples here, I understand that, but this is ongoing research.

Type D, or brand D, again, no difference. In fact, it looked a little bit just the opposite. But with brand E, one failure with no flushing but three failures with flushing.

But there are some other problems with flushing. When you put spores inside of a turbine chamber and then hook it up to an air/water system and you operate it, what happens to those spores? Some of them come out--

DR. ROBERTSON: A good question. What happens to those spores?

DR. MILLER: I don't know for sure, but we can't recover nearly as many. So what are their choices? One, they're killed by what some friends of mine at CDC have referred to as centrifugal sterilization. You just blast them against the side of the turbine chamber wall and smash them, but that's being facetious. Secondly, they're going to come out the end cap, and thirdly, out the exhaust air line, and maybe a little bit out the bur shaft.

But whatever happens to them, look here. Again, just testing here, recovery of spores, with and without pre-flushing--this is just inoculated and then pre-flushed and

then the spores were recovered. This also tells you how good our recovery system is of flushing the handpiece turbine with 4.0 mL ten times.

Brand B, no pre-flushing, we put in 3.8 times ten-to-the-sixth spores per handpiece and we recovered 0.6 times ten-to-the-sixth handpieces, which is a 17 percent recovery with our normal recovery system. If we pre-flushed that handpiece, though, we only recovered 4,000 spores, 0.1 percent, so a tremendous loss of your challenge by pre-flushing.

Similar situations with brand D. We recovered without our pre-flushing system 29 percent of the spores we put on there and very little after pre-flushing.

And here we got, which is not too bad, 55 percent recovery of the spores. I know it would be nice if we could recover 90 percent of them, but in this particular instance, we didn't.

So while pre-flushing may tend to blow the spores around and create a pretty serious challenge, you've got this other problem that you're losing some and you don't know where they're going and you don't know what's happening to them, and that's not a good thing to have in a validation test.

Another question: Is it important to have blood

with spores? What effect does that have on sterilization, killing of the spores inside of the turbine chamber? Again, effective on killing spores on handpiece turbines, we put, again, a little over six logs of spores into each handpiece.

Brand B, no blood, processed at 121 degrees Centigrade for 15 minutes, one of five failures. With blood, same thing, no difference. Of brand D, there was a difference. One out of five failure without blood but three out of five failures with blood. The same thing for brand E.

So it looks like, at least with some handpieces, the presence of blood presents a more difficult challenge, and this is not new information. This information is available in many past kinds of studies. Blood presents--or an organic material presents a more difficult challenge.

So here is what we have using blood and no pre-flushing, to show you a comparison here of three brands of handpieces. Killing of spores in blood on handpiece turbines with no pre-flushing, the challenge in each instance was 3.8 million spores per handpiece, and this, of course, again, is the number of handpieces that failed versus the total number tested.

Type B, under the gravity steam sterilizer, 121 degrees Centigrade for 15 minutes, one of five failures, one

of three failures, and three of five failures.

Same steam sterilizer but boosted up at 134 degrees Centigrade, and if you'll notice here, these times are what we referred to as half-cycles, half the normal recommended cycle. At 134 degrees Centigrade at two-and-a-half minutes, one of five failures, none of five, none of five.

In the unsaturated chemical vapor sterilizer, in their half cycle, one of five, three of five failures, and zero of five failures.

Yes?

DR. GREENSPAN: Did you look, and it may be your next slide, but in case it isn't, did you look at when you go to full time as opposed to choosing this--

DR. MILLER: Not in this particular series of studies. In the previous ones where we went at 121 degrees Centigrade for 30 minutes, we found that we still couldn't get--we had 29 percent failures of the 48 handpieces.

That's the information I care to present on high speeds. Now I have some additional information on slow speeds. Would you like for me to go ahead and present that now?

DR. ROBERTSON: Surely.

DR. MILLER: Okay. Potential for cross

contamination with the slow-speed handpiece, again, acknowledge my coworkers.

The purpose of this series of studies was to determine if the inside of slow-speed handpiece/prophy angle systems can become contaminated during use, and if so, possibly indicate that the entire system should be heat processed rather than covered or surface disinfected.

Method: One type of slow-speed motor was used here with six types of disposable and two types of reusable prophy angles. The motors and the nose cones and the reusable prophy angles, anything that could be was steam sterilized prior to use, and obviously, the disposable prophy angles weren't. That steam sterilization here, by the way, was 134 degrees at 30 minutes, a serious steam challenge. And again, sterility was confirmed prior to testing.

The methods here were performed in replicates of 20. In other words, each time we did a test, we did 20 units, 20 motors with nose cones and prophy angles attached. That was one test system.

Two methods: The first method, we put a test contaminant in the laboratory in the prophy angel and we looked at its route of spread from the prophy angle up inside to the gears of the motor. In the second method, we

inoculated the test organism on the gears of the motor and looked for its spread during operation down through the handpiece to the prophy angle and even out. So we looked at contamination coming from the prophy angle up as well as from the gears of the motor back down.

In method one, when we went from the angle to the motor, we had a handpiece--HP stands for handpiece/prophy angle system--wrapped up in plastic. So we had the whole thing connected, ready to go, as if it were going to be used on a patient, and we wrapped the entire outside with Saran wrap to make sure that any internal contamination came from the inside, not the outside.

The head of the handpiece system, or the prophy angle, I should say, was submerged in a test bacterium, Serratia marcescens. This particular bacterium is a gram negative rod. We use it because when it grows at room temperature, it produces a very vivid red pigment and we can detect it from other kinds of possible contaminants. So it's a marker organism, but similar to many gram negative rods that are elsewhere in the human body and nature.

So after we submerged the head into the suspension of this bacterium, we turned it on and we pressed the prophy cup up against the side of the beaker 30 times in a minute to simulate actual stress of the prophy cup during use.

Again, this is a pictorial of what we did. This is the handpiece/prophy angle system all wrapped up in plastic. There's the culture of the test bacterium here. We submerged the prophy cup in there, operated it for a minute, pressing the prophy cup against the side of the wall to stress it 30 times in that minute, and we carefully blotted off the outside of it.

We aseptically disassembled the handpiece. We sampled the inside shaft of the prophy angle. We then sampled the inside of the nose cone. These were not quantitative recovery procedures. We sampled the gears of the nose cone and the gears of the motor to see if the test bacterium got in the prophy angle and traveled up all the way.

Again, a sample of what we did. After it was aseptically disassembled, simply taking a paper point and swabbing it around the shaft of that prophy angle, again, non-quantitative culturing.

Sampling the gears of the nose cone that actually connect to the gears of the motor, non-quantitative, and then sampling the gears of the actual handpiece motor to see if the organism could be detected there.

The samples were then placed into--the paper points were then swabbed onto an auger plate and then--or

the swabs, and then the swab and the point were again dropped totally into broth medium and bortex to make sure we could recover any organisms that may be present. Then any growth that was detected was confirmed to be that of the test organism. We also did sterilized sham, in this particular case, no inoculation, because this organism could, by chance, may be a contaminant in the environment, and found no presence of the organism except when we put it there.

DR. ROBERTSON: So you sampled the lab top or something?

DR. MILLER: That's right. We do this in a biosafety hood, a laminar air flow system.

That's just showing culturing of the paper point and dropping them in fluid and incubation.

Results: Presence of internal contamination when inoculated at the prophy angle end, and these data represent a percent of the 20 systems that became contaminated, and this is the particular prophy angle we used. You can see here we've used brand names because we're using just about anything we could find out there in the marketplace. "D" stands for the disposable prophy angle. "R" stands for reusables.

Culturing the inside of the prophy angle, for

example, in this first one, we found inside of the 30 percent of those prophy angles had the test organism inside. In 15 percent of them, we found the organism in the nose gears. And in 40 percent of them, we found organisms present in the motor gears that came all the way up through the inside system to contaminate the gears of the motor.

The same brand here, again, a separate study with these 20 handpieces. Twenty percent inside the angle, zero here in the nose cone, and again, this is not quantitative recovery in any of these cases, just sampling for the presence or absence, and we certainly could miss some. Five percent here, and on down the list.

Really, the most important, I think, concern is, do they get all the way up to those gears of that motor? And in many instances, they do. If you look at the total number here of positives, this one slide represents a total of 220 tests. And of those 220 tests, 32, or 15 percent, ended up with contamination in the gears of the motor.

Are there any questions on what we're showing here?

DR. ROBERTSON: What percent of the controls were positive?

DR. MILLER: None. Of the sham inoculated controls, none, and that was--yes?

DR. PATTERS: Just how did you sterilize the motor to begin with?

DR. MILLER: At 134 degrees Centigrade at 30 minutes in steam, and then we also cultured those to verify that they did not have the test bacterium present.

DR. PATTERS: You did that?

DR. MILLER: Yes, absolutely.

Any other questions before we look at the reverse of this?

[No response.]

DR. MILLER: The thinking is, in using a handpiece, are the organisms present on saliva going to get up inside and contaminate the inside of the motor, the gears of the motor? And apparently they do in some instances here, as you can see.

Then the next question is, well, if they're up there, can they get back out into the mouth of the next patient? So we again put the test organism now on the gears of the motor and tested to see if it would travel back down through the handpiece system and come out the prophy angle.

In this particular case, again, the gears of the motor inoculated with Serratia marcescens. The handpiece/prophy angle system was wrapped in plastic. The head was submerged now in sterile water as a recovery fluid.

It was turned on for one minute and the prophy cup stressed against the side of the test tube 30 times in that one minute, and then that water was then cultured.

But again, here we're placing now the inoculum on the handpiece motor gears. That's where the nose cone attaches to, right there. We put it all together, wrap it up, and be careful that will eliminate any outside contamination, put it in sterile water, operate it, and then we'll culture this sterile water for the presence of the test organism as well as the inside of the prophy angle and the nose cone by the same systems that we described before. Again, not quantitative culturing, but the results.

So again, presence of internal and external contamination when inoculated at the motor gears, percent of the 20 systems that became contaminated. Here, the inside of the nose cone, 15 percent of those 20, or three of those 20, became contaminated inside of the angle, none, none, and so forth down the line.

Exit through the prophy angle, this is the recovery of the organisms that are coming out of the prophy angle into the sterile water. This is what ended up inside of the prophy angle from the motor gears. Again, collectively, this slide represents 200 tests, of which 35 of the tests were positive in this column here, coming out

of the prophy angle, which is 18 percent. Again, quite variable, but appears to occur in some degree in all systems.

Lots of other studies need to be done, and this basically concludes what I have to say.

DR. ROBERTSON: Thank you, Chris.

Maybe before we take the break, while Chris is still here and has his slides up, we'll take questions from the panel.

DR. ROSAN: Chris, was there some consistency in the contamination? In other words, if you found it in your nose, did you find it in the other parts, or would these represent different sorts of things?

DR. MILLER: There was some degree of consistency, but since we didn't have a quantitative flush of a particular site, you can't really make any inferences, and I don't know how to quantitatively recover from the inside of the nose cone. That's my problem. It's a real tough situation there.

But I can tell you, I don't know how many times we attempted to verify that these were false results. We looked at all possible routes of contamination. We covered our handpiece system and put the test organism on the outside of the Saran wrap to see if there's any way it could

get inside. We really--and now we're into trying to do quantitative tests. How many organisms are getting back inside and how many are coming back out? Again, you have to have a quantitative recovery system.

The two tests that we have done quantitatively, we have put the organisms on the gears and then tested quantitatively the sterile water at the other end, and we've come up with 100 CFUs of organism in three of the 20 handpieces that were positive. And that's just one test now, so it doesn't appear that there's a tremendous amount of influx of these organisms, but at least enough to warrant some concern.

DR. ROBERTSON: Dr. Patters?

DR. PATTERS: Chris, based on the sum total of your experiments using the both high-speed and slow-speed handpieces that you handled, do you feel that using standard autoclave practice, 121 degrees, 30 minutes, that you could sterilize the inside of a handpiece?

DR. MILLER: It depends upon how we will define sterilization. If we define it as I understand it in accepting the sterilizability that FDA is concerned about, then I think the answer would be, no, we can't guarantee that we will sterilize it under those conditions, but maybe at 134 degrees Centigrade for 30 minutes.

DR. PATTERS: Sterile is like pregnant. You are or you're not.

DR. MILLER: And if you assume that the test organism is--we showed that we could sterilize salivary bacteria, okay, but not bacterial spores.

DR. GREENSPAN: And that's viruses.

DR. MILLER: You understand what I'm saying.

DR. PATTERS: I do. You're saying you cannot.

DR. MILLER: Not bacterial spores, right. But on the other hand, I think that what is being done is reasonably okay because at least we can kill some salivary organisms. I understand, the hallmark is the spore, and that's what you must gauge everything on. I understand that very well.

DR. PATTERS: What it tells you is that there are certain parts of the handpiece that do not reach 121 degrees Centigrade and one atmosphere of pressure for 30 minutes or the spores would be dead, because they'll be dead--if you put them on a plate, they'll be dead.

DR. MILLER: Right. And again, remember how I'm coming to you with one particular steam sterilizer that was in use and these particular brands of handpieces.

DR. ROBERTSON: That was very nice, and I think it does ask questions, anyway.

DR. MILLER: Yes, absolutely.

DR. ROBERTSON: When you did the sterilization experiments, did you run parallel spore strips outside the handpieces?

DR. MILLER: Oh, yes, in every cycle.

DR. ROBERTSON: And you then cultured that spore strip as well? I didn't see any of that data.

DR. MILLER: No, it's not up in the slides, but that's standard practice.

DR. ROBERTSON: It's kind of important, because--

DR. MILLER: Oh, absolutely, and--

DR. GREENSPAN: He said it at the beginning.

DR. MILLER: And in addition to that, periodically, we would also put the actual spore strip, yes, but in addition to that spore strip, we would also place the same volume of spores put into the handpiece on a piece of aluminum foil and place that in the chamber, as well, so at least we could test if we could kill that same exact volume of spores in blood when it had total access to the steam, and we always did, under all of those conditions.

DR. ROBERTSON: The data wasn't there, but you've done it, and in the future, that control data will appear?

DR. MILLER: When this is published, that control data will lead the list.

DR. ROBERTSON: Good. And while you're doing controls, you're going to, for either putting the spore strips that you've cut up and stuffing them into the handpiece, you're also going to stuff into the handpiece some strips which have no spores on them?

DR. MILLER: We probably won't ever be doing that kind of testing again. I don't think it's a real good--

DR. ROBERTSON: But if you did that--

DR. MILLER: But I understand what you're saying.

DR. ROBERTSON: If you did do that again, you'd want to be sure that you had a control in which there were no spores initially, and when you inoculated your turbine fins, you'd want to inoculate your turbine spins with oatmeal or something that was sterile that didn't have any spores in it and run that in parallel, as well.

DR. MILLER: As an environmental check, yes.

DR. ROBERTSON: Well, if you're--

DR. MILLER: I don't know where else they'd come from.

DR. ROBERTSON: If you're floating spores around--

DR. MILLER: Well, they're out there. You've got to have it on the outside, yes.

DR. ROBERTSON: You've got to have a control. Otherwise, I don't know what to do with your positive

results.

Yes, Deborah?

DR. GREENSPAN: You had no problem killing the spore strips in the handpiece, and presuming, then, that the center of the handpiece without the turbine reached 121 degrees Centigrade for that period of time, can you speculate why you think the autoclave cycles, and, indeed, the chemclave cycles, are not killing the spores?

DR. MILLER: When spores are placed on strips or anything else, we refer to whatever they're placed on as a carrier, and I think the carrier can influence, really, the true resistance of a spore when exposed to some sterilizing agent. The spore strips, in actuality, when you put a spore strip in a sterilizer with nothing else in there or fully exposed to the steam, as it turns out, in many instances, those spores are killed before it even reaches temperature, okay?

That's the way it is in real life when you do these kinds of studies. By the time the sterilizer gets up to temperature, there has been enough heat there to kill most of the spores within a matter of a very few seconds afterwards. So the carriers are different.

And I'll be honest with you. I've never done what we call D-value testing or validation of the resistance of

spores in a suspension on handpieces, in other words, done the incremental time exposure and then culture the number of spores still alive to calculate a D-value, which is a measure of the resistance of the spores, and that's a stated fact when you buy a spore strip.

It comes with a D-value from one to two minutes, but it's a totally different carrier, totally different environment that we're dealing with here, between spore strips and spores actually dried onto a metal surface. The heat-up of the metal is going to change things, versus the heat-up of the paper, strips, lots of variability.

DR. ROBERTSON: Other questions?

[No response.]

DR. ROBERTSON: Chris, thank you very much.

DR. MILLER: Sure.

DR. ROBERTSON: We will take a break until 4:00.

[Break.]

DR. ROBERTSON: Let us begin. Carolyn, you are assembling a table down there.

DR. TYLENDA: Dr. Mulry, if you would join Dr. Mendelson and Dr. Kuehne at the table, we would appreciate it. Kevin, could you pull up one more chair for Dr. Miller? Thank you.

[Pause.]

DR. ROBERTSON: I was kind of waiting for Dr. Miller, as well, because I thought we could tail off of his presentation.

[Pause.]

OPEN COMMITTEE DISCUSSION

DR. ROBERTSON: Thank you for joining us, Chris.

I thought we might actually continue on from your presentation and everybody can jump in here. Your preliminary data certainly suggests the possibility that standard sterilization at present pressure and temperature could--it is possible that that process will not sterilize, by our presently-accepted definitions, the interior surface of handpieces.

DR. MILLER: Some of the lower-cycle conditions, time and temperature. Some of the higher-cycle conditions looked pretty good in the tests, in other words, 134 degrees Centigrade for 30 minutes, versus 121 for 15.

DR. ROBERTSON: Well, Mark said to you, under present conditions of sterilization, do you think that those processes sterilize all handpieces?

DR. MILLER: If you're looking for a 100 percent positive answer, the answer is no.

DR. ROBERTSON: But that was based on spores.

DR. MILLER: That's correct.

DR. ROBERTSON: What that has done is, I think, set up for you a very nice hypothesis. There was preliminary data we saw, and you now have, I assume, gone like a bat based on that preliminary data to do definitive studies on the sterilizability of handpieces. But based on that data, the implications of that are that it is possible that more rigorous sterilization procedures may be necessary for sterilization of handpieces.

DR. MILLER: That's a possibility, which makes the authors--that's important to the authors, it seems to me, of this guidance document, because one of the critical issues here is sterilization of the handpiece, such that that handpiece is not, as was suggested, one of the primary health hazards, a source of contamination.

DR. ROSAN: I just have a question about one of the conditions. Were those handpieces lubricated?

DR. MILLER: Yes.

DR. ROSAN: So they were oiled?

DR. MILLER: Yes. The handpieces were processed according to the manufacturer's directions before they were inoculated. So if they had to be sprayed before and after the previous sterilization, they were, or whatever the recommendations were, with the cleaner or lubricant. So in those that were regularly oiled, they had oil in them at the

time we put the spores on.

MR. ULATOWSKI: Mr. Chairman, a comment. I think Dr. Miller's data highlights one of the dilemmas in evaluating 510(k)s and how the guidance document will be implemented by manufacturers in regard to validating sterilization processes. If there is not a canned process, a cook book procedure for validation, and one accepts and relies upon data submitted by the manufacturers, you can get almost any result you want to get, depending on how you do your validation study. We see enormous variability in the manner in which devices are subject to validation and conflicting data, in many cases.

It is very troublesome to us. I think it is an area that deserves standardization and additional work by the manufacturing community, and we would solicit their help in regard to that through some standard-setting organization or whatever.

DR. NORMAN: Paul, might I ask Chris a question? As you look at the processes that you have been through, is cleaning more of a necessary step in sterilization than has been advocated, do you believe?

DR. MILLER: I think cleaning is an extremely important step, and as I look at it, from somebody interested in infection control and disease prevention,

cleaning is to be done to reduce the total bioburden down as low as possible so that when you get to the sterilization step, there will be as few organisms left as possible to kill. So cleaning is very, very important.

DR. NORMAN: Do you intend to include things like ultrasonic cleaning prior to this and removing of oil and a few steps like this in your process to more fully define the problems of sterilization?

DR. MILLER: That's a very good point. It's difficult for me, for example, to automatically do ultrasonic cleaning on handpieces which the manufacturers do not recommend. So that kind of information, probably, the best way to clean things, probably has to come from manufacturers. But nevertheless, the process has to be done. It's very important to define how things have to be cleaned prior to sterilization.

DR. ROBERTSON: Following up on your point, the manufacturers' kind of standards, it seems to me that I would not have expected the result that Dr. Miller reported.

MR. ULATOWSKI: I have seen Dr. Miller's data and it was troublesome, yes.

DR. ROBERTSON: Well, no--

MR. ULATOWSKI: Disturbing.

DR. ROBERTSON: Yes, yes. I would not have

expected his answer to be less than 100 percent of the handpieces were rendered sterile by that method. I mean, I think that's absolutely wonderful because that's what science is all about, and I'm thrilled because it opens up an area to really ask good questions about. But if we are not even sure, I couldn't blame the manufacturers for not coming up with that appropriate methodology. I would have guessed that the standard method of sterilization would have been sufficient. I worry a little bit about writing a guidance document based on information you don't know.

Deborah?

DR. GREENSPAN: I'd like some clarification about the guidance document for the manufacturers requiring that handpieces can be sterilized. Are the manufacturers then required to produce their own documentation showing that they, in fact, can effectively sterilize a handpiece?

MR. ULATOWSKI: As part of the validation process of the sterilization instructions, they are required to conduct tests to show that the product can be sterilized and to maintain the records at their facilities indicating that that is the case.

DR. GREENSPAN: They would be required to do this sort of tests, along the line of what Dr. Miller described?

MR. ULATOWSKI: Yes, exactly, exactly, without

doubt.

DR. TYLENDA: And we ask the manufacturers that they make sure that the instructions for sterilization are included in the instructional material that accompanies the handpiece and that those conditions are the same conditions used in the validation studies, which seems--I mean, you would think that would be obvious, but we have seen cases where that hasn't happened. So we specifically ask that that be put in the instructional manual.

DR. ROSAN: But that seems to create a real problem, because with what we see here, there could be enough variation in perhaps even the sterilizer, so that if you have to follow the manufacturer's recommendation, you have to buy the same sterilizer, the same capacity. It's really an enormous problem, I think, in terms of how that's going to be done. I think we do need to get some real standardization here so that we don't have all these kinds of things to discuss.

MR. ULATOWSKI: We have come a long way in infection control procedures even over the last few years, and with regard to steam, it's been somewhat of a naive approach to instructions for use, reprocessing with steam, by manufacturers saying resterilize with steam, when we know there's many types of steam sterilizers and cycle conditions

and all may not be effective. So we asked for more rigor in terms of testing under controlled conditions to specify the types of procedures and processes that are necessary.

DR. KUEHNE: I just wanted to comment. I think we ought to make a distinction between something which can be autoclaved versus something which can be sterilized versus something which is always going to be sterilized. Like you pointed out, it depends upon the testing methodology that you use. You can pretty much come up with whatever you want to.

Dr. Miller has presented evidence to show that under a broad range of clinical conditions, we can't be sure that 100 percent of handpieces are actually achieving sterility by our present definition. However, we can require, at the very--and the fallout of that is going to come over the next few years as we do more testing and research to show the different effects.

But what we can right now require, in fact, is to show that the handpieces that are made can, in fact, be autoclaved or chemclaved. In other words, the materials will withstand the conditions the manufacturer has recommended. The handpiece will withstand 134 degrees for 30 minutes and still function properly. That doesn't assure that in every clinical condition, bioload, they will

actually be sterilized, but they can be autoclaved.

The second thing you can require is that under some test conditions which are reasonable, you can achieve sterility, again, without the assurance it's always going to happen 100 percent.

Does that help?

MR. ULATOWSKI: Yes, very much so.

DR. ROBERTSON: That may be helpful, but I guess I disagree with it.

[Laughter.]

DR. ROBERTSON: From my perspective, Dr. Miller's data says we need to ask the question. That's what the data says. If it turns out that, in fact, handpieces can't be sterilized at a certain standard pressure and temperature, then I'm not sure why you'd go through the motions of asking manufacturers to meet the standard specification. What you have to do is develop either a new methodology to sterilize handpieces so you're assured that they are sterilizable or you've got to build handpieces to a different standard which the science says will sterilize them.

So I think until we know, in fact, that a standard autoclave procedure will, in fact, sterilize handpieces, I'm not sure why you'd set that up as a guidance standard. I think you have to know that first. And all Chris's data